their childbearing years may be included in the claim. Information contained in paragraph (b)(3) of this section may be used. If such an estimate (i.e., 50 percent) is provided, the estimate shall be accompanied by additional information that states that the estimate is population-based and that it does not reflect risk reduction that may be experienced by individual women.

(vii) *Diets adequate in folate.* The claim may identify diets adequate in folate by using phrases such as ''Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, whole grain products, fortified cereals, or dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables, legumes, whole grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement.''

(d) *Model health claims.* The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Examples 1 and 2.* Model health claims appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit (general population). The examples contain only the required elements:

(i) Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(ii) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(2) *Example 3.* Model health claim appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit. The example contains all required elements plus optional information: Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

(3) *Example 4.* Model health claim appropriate for foods intended for use by the general population and containing more than 100 percent of the DV of folate per serving or per unit: Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg).

[61 FR 8779, Mar. 5, 1996; 61 FR 48529, Sept. 13, 1996, as amended at 65 FR 58918, Oct. 3, 2000]

§ 101.80 Health claims: dietary sugar alcohols and dental caries.

(a) *Relationship between dietary carbohydrates and dental caries.* (1) Dental caries, or tooth decay, is a disease caused by many factors. Both environmental and genetic factors can affect the development of dental caries. Risk factors include tooth enamel crystal structure and mineral content, plaque quantity and quality, saliva quantity and quality, individual immune response, types and physical characteristics of foods consumed, eating behaviors, presence of acid producing oral bacteria, and cultural influences.

(2) The relationship between consumption of fermentable carbohydrates, i.e., dietary sugars and starches, and tooth decay is well established. Sucrose, also known as sugar, is one of the most, but not the only, cariogenic sugars in the diet. Bacteria found in the mouth are able to metabolize most dietary carbohydrates, producing acid and forming dental plaque. The more frequent and longer the exposure of teeth to dietary sugars and starches, the greater the risk for tooth decay.

(3) Dental caries continues to affect a large proportion of Americans. Although there has been a decline in the prevalence of dental caries among children in the United States, the disease remains widespread throughout the population, imposing a substantial burden on Americans. Recent Federal government dietary guidelines recommend that Americans choose diets that are moderate in sugars and avoid excessive snacking. Frequent between-meal

snacks that are high in sugars and starches may be more harmful to teeth than eating such foods at meals and then brushing.

(4) Sugar alcohols can be used as sweeteners to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and certain confectioneries. Dietary sugar alcohols are significantly less cariogenic than dietary sugars and other fermentable carbohydrates.

(b) *Significance of the relationship between sugar alcohols and dental caries.* Sugar alcohols do not promote dental caries. Sugar alcohols are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met, except that sugar alcohol-containing foods are exempt from section §101.14(e)(6).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim relating sugar alcohols, compared to other carbohydrates, and the nonpromotion of dental caries may be made on the label or labeling of a food described in (c)(2)(ii) of this section, provided that:

(A) The claim shall state that frequent between-meal consumption of foods high in sugars and starches can promote tooth decay.

(B) The claim shall state that the sugar alcohol present in the food ''does not promote,'' ''may reduce the risk of,'' ''useful [or is useful] in not promoting,'' or ''expressly [or is expressly] for not promoting'' dental caries;

(C) In specifying the nutrient, the claim shall state ''sugar alcohol,'' ''sugar alcohols,'' or the name or names of the sugar alcohols, e.g., ''sorbitol.''

(D) In specifying the disease, the claim uses the following terms: ''dental caries'' or ''tooth decay.''

(E) The claim shall not attribute any degree of the reduction in risk of dental caries to the use of the sugar alcohol-containing food.

(F) The claim shall not imply that consuming sugar alcohol-containing foods is the only recognized means of achieving a reduced risk of dental caries.

(G) Packages with less than 15 square inches of surface area available for labeling are exempt from paragraphs (A) and (C) of this section.

(ii) *Nature of the food.* (A) The food shall meet the requirement in §101.60(c)(1)(i) with respect to sugars content.

(B) The sugar alcohol in the food shall be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these.

(C) When fermentable carbohydrates are present in the sugar alcohol-containing food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in ''Identification of Low Caries Risk Dietary Components,'' T. N. Imfeld, Volume 11, *Monographs in Oral Science*, 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Karger AG Publishing Co., P. O. Box, Ch-4009 Basel, Switzerland, or may be examined at the Center for Food Safey and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which describe the relationship between diets containing sugar alcohols and dental caries.

(2) The claim may indicate that development of dental caries depends on many factors and may identify one or more of the following risk factors for dental caries: Frequent consumption of fermentable carbohydrates, such as dietary sugars and starches; presence of oral bacteria capable of fermenting carbohydrates; length of time fermentable carbohydrates are in contact with the teeth; lack of exposure to fluoride; individual susceptibility; socioeconomic and cultural factors; and characteristics of tooth enamel, saliva, and plaque.

(3) The claim may indicate that oral hygiene and proper dental care may help to reduce the risk of dental disease.

(4) The claim may indicate that the sugar alcohol serves as a sweetener.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between sugar alcohol-containing foods and dental caries.

(1) Example of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

[61 FR 43446, Aug. 23, 1996, as amended at 62 FR 63655, Dec. 2, 1997; 66 FR 66742, Dec. 27, 2001]

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from certain foods to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Soluble fiber from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met. The label and labeling of foods containing